

REMARKS

Claims 2-12 have been canceled in this response.

Claims 1, 13- 30 are pending in the present application.

New claims 31-48 have been added.

Claim 1 has been amended by inserting a proviso into step 1 and inserting the term “randomly” into step 2. Support for the amendments can be found in paragraphs [0055] and [0062] of the Specification.

Claim 16 has been amended by altering the claim dependency. Further support for the amendment can be found in claim 15.

Claim 22 has been amended by changing the dependency.

Support for new claim 31 can be found in paragraph [0060] of the Specification.

Support for new claims 32-48 can be found in original claims 2-10.

No new matter has been added.

Effective Filing Date

The Examiner states that the effective filing date of the instant application is December 24, 2003. However, the filing date of the foreign priority document JP 2003-364682 is October 24, 2003, as can be seen from the attached first page of the Official Filing Receipt.

Claim Objections

The Examiner has objected to claims 5-12 as improper multiple multiply dependent claims. Applicants have canceled claims 5-12, thereby obviating the rejection.

Information Disclosure Statement

The Examiner notes that the Office does not have record of the foreign patent and non-patent literature documents listed on the Information Disclosure Statement of April 21, 2006. Applicants submit herewith a new Information Disclosure Statement and copies of all foreign patent and non-patent literature documents listed thereon.

Rejections Under 35 USC § 102

*Kawasaki et al. (US 6,521,408)*

The Examiner has rejected claim 1 as anticipated by Kawasaki et al. (US 6,521,408). The Examiner contends that Kawasaki et al. teaches a method of plant transformation with *Agrobacterium* comprising genomic fragments contained in a genomic library, where the plant to be transformed is deficient in some function, followed by selection of transformed plants which exhibit a restored function due to the presence of a particular genomic fragment, the plants having been identified as containing the genomic fragment. Applicants respectfully traverse.

Kawasaki et al. describe a complementation test performed by a genomic DNA library constructed using a high capacity binary vector. The complementation test of Kawaski et al. is performed for the purpose of determining location of a certain gene with known function, by determining whether the known function of the target gene is complemented. Kawasaki et al. fails to teach or suggest the prominent features of instant claim 1; that is, constructing a genomic library without “a preliminary selection step of the genomic DNA fragments” and “randomly” introducing the genomic fragments.

Applicants note that amended claim 1 requires that no preliminary selection of the genomic DNA fragments is conducted. Paragraph [0055] of the Specification states “in order to eliminate any deviation to occur in the chosen candidate fragments, it is desirable that the genomic DNA fragments to be introduced into the plant are not subjected to such a preliminary selection before they are introduced into the plant.” Consequently, claim 1 now indicates that any

selection which eliminates the genetic diversity of the genomic DNA library should not be performed on the basis of the genetic information of the donor (original) plant, which coincides with the description in paragraph [0056] of the Specification.

Furthermore, step 2 of amended claim 1 requires “introducing the genomic fragment ...separately and randomly...” Paragraph [0062] of the Specification describes that “in a population of plants into which genomic DNA fragments were randomly introduced, the distribution of measured values is expected to become broader.” In addition, the paragraph states that “by selecting the plants that present the values of measurement located at one or both ends of the distribution, one can obtain a smaller population including plants that contain genomic DNA fragments that bring about a phenotypic variation.” Such statements relating to random introduction coincide with descriptions in paragraphs [0044] – [0047] in which introduction of arbitrary genomic DNA fragments are described.

Thus, because claim 1 requires that a library of genomic DNA fragments are prepared without a preliminary selection step for the DNA fragment, whose function is unknown, is randomly introduced into a plant, claim 1 cannot be anticipated by the Kawasaki et al. reference which is concerned with genes having known function. In view of the above, Applicants respectfully request reconsideration and removal of the rejection.

*Lazo et al. (1991)*

The Examiner has rejected claims 1-2 as anticipated by Lazo et al. (1991). The Examiner contends that Lazo et al. teach a method of plant transformation with *Agrobacterium* comprising phage cosmid cloning vectors comprising 15-20 kb fragments of *Arabidopsis* genomic DNA, where transformed plants exhibited the agriculturally advantageous trait of herbicide resistance and where successive testing of progeny allow for the identification of the particular genomic clone conferring resistance (i.e. selection of the particular genomic fragment). Applicants respectfully traverse.

As a preliminary comment, Applicants have canceled claim 2, thereby obviating that rejection.

Lazo et al. describe plant transformation with an herbicide resistance gene derived from the *Arabidopsis* GH50K strain. That is, according to the technique described in Lazo et al., the function of the gene used for the plant transformation is known (i.e. herbicide resistance). Consequently, Lazo et al. fail to disclose constructing a genomic library without a preliminary selection step for the genomic DNA fragment and introducing the genomic fragments “randomly” as required by claim 1.

Applicants also point out that new claim 31, which finds support in original claim 2 and is dependent on claim 1, requires the method to be “independent of the characteristics of the plant which is a donor of the genomic DNA fragments and the genomic DNA fragments that are introduced.” Paragraph [0056] of the Specification states “in the present invention there is no need to have information about the genomic DNA fragments to be introduced, in particular, the phenotype with which said genomic DNA fragments are associated in the original plant. This is because it is not until the phenotype of the transgenic plant is selected that a useful genomic DNA fragment is specified.” Consequently, to achieve the present invention, it is not necessary to possess information on the genomic DNA fragments to be introduced. In addition, genomic DNA fragments having a new function can be obtained independently of the characteristics of a donor (original) plant by selecting genomic DNA fragments that produce a plant having an agriculturally advantageous phenotypic variation.

In view of the above, Applicants request reconsideration and removal of the rejections.

Olszewski et al (1998)

The Examiner has rejected claims 1-4 as anticipated by Olszewski et al. (1998). The Examiner contends that Olszewski et al. teach the biological transformation of tobacco cells with an *Agrobacterium* bacterial strain, comprising a plasmid having 15-20 kb of *Arabidopsis* genomic DNA cloned in cosmid vectors and then transferred to *Agrobacterium*, where whole

tobacco plants were regenerated from the transformed cells, genomic DNA was isolated from the transgenic plants and where the isolated genomic DNA fragment was selected that correlated with improved growth in the presence of herbicide. Applicants respectfully traverse.

As a preliminary comment, Applicants have canceled claims 2-4, thereby obviating those rejections.

Olszewski et al. teach transformation of tobacco with the AHAS gene derived from *Arabidopsis*. As the AHAS gene is known as an herbicide resistance gene, the technique disclosed in Olszewski et al. is plant transformation by a gene with a known function, and fails to disclose constructing a genomic library with preliminary selection step for the genomic DNA fragment and introducing the genomic fragments randomly, as required by the claim 1. Consequently, for this reason and the reasons discussed in the other sections above, Applicants request reconsideration and removal of the rejection.

#### Rejections Under 35 USC § 103

*Kawasaki et al in combination with Hamilton et al., Frary et al (1996) and Tigchelaar et al. (1978)*

The Examiner has rejected claims 1-4 as obvious over Kawasaki et al in combination with Hamilton et al., Frary et al (1996) and Tigchelaar et al. (1978). The Examiner's interpretation of the Kawasaki et al. reference is detailed above. The Examiner admits that Kawasaki et al. do not teach the transformation of isolated plant cells or plant cell cultures, followed by regeneration of a whole transformed plant.

Regarding Hamilton et al., the Examiner contends that the reference teaches the production of tomato genomic DNA fragments at least 100 kb in size in a library of cloning/plant transformation *Agrobacterium* vectors for identification of agricultural genes of interest via tomato transformation and phenotypic complementation.

The Examiner contends that Frary et al. teach *Agrobacterium*-mediated transformation of tomato tissue explants containing cells, followed by the regeneration of whole transgenic tomato plants.

With respect to Tigchelaar et al., the Examiner contends that the reference teaches tomato mutants with delayed ripening, due to the mutation of ripening genes, where ripening involves the degradation of fruit tissue by the enzyme polygalacturonase and the production of carotenoid compounds and flavor-conferring compounds (e.g. an “agriculturally advantageous” trait).

From these references the Examiner concludes that the skilled artisan would have found it obvious to use the transformation-mediated method of plant transformation with genomic DNA fragments from a DNA library taught by Kawasaki and to modify that method by incorporating the tomato genomic DNA library taught by Hamilton et al., the *Agrobacterium*-mediated tomato transformation method taught by Frary et al. and the tomato ripening mutant plants taught by Tigchelaar et al. for the selection of those genomic clones containing ripening genes given the suggestion by Kawasaki to broadly apply their methods to dicots and by Hamilton et al.’s suggestion to use *Agrobacterium*-mediated transformation of plants with genomic fragments for the identification of new agriculturally advantageous genes via phenotypic complementation. Applicants respectfully traverse.

As a preliminary matter, Applicants note that claims 2-4 have been canceled, thereby obviating the rejections based on these claims.

Hamilton et al. disclose the preparation of a BAC vector comprising large fragments of tomato genomic DNA and *Agrobacterium*-mediated tomato transformation using the vector.

Frary et al. disclose efficient transformation of tomato via an *Agrobacterium*-mediated method, followed by regeneration of whole transgenic plants.

Tigchelaar et al. disclose genes involved in regulation of tomato ripening.

As discussed above for anticipation, the complementation test disclosed in Kawasaki et al. is performed to determine the location of a gene with known function and fails to teach or suggest the essential feature of the present invention, also described above under anticipation. As Hamilton et al., Frary et al. or Tigchelaar et al. do not compensate for the failure of Kawasaki et al., the Examiner has failed to present a prima facie case of obviousness. Thus, Applicants respectfully request reconsideration and removal of the rejection.

*Hamilton (US 5,997,439) in combination with Hamilton et al. (1999), Frary et al. (1996) and Tigchelaar et al. (1978).*

The Examiner has rejected claims 1-4 as obvious over Hamilton (US 5,997,439) in combination with Hamilton et al. (1999), Frary et al. (1996) and Tigchelaar et al. (1978). The Examiner contends that Hamilton teaches a cloning vector comprising large fragments of tomato genomic DNA contained in a genomic library, and suggests using this with *Agrobacterium*-mediated tomato transformation for the identification of agriculturally advantageous genes from the genomic fragments via phenotype complementation where the genomic fragment containing the agriculturally advantageous gene can be identified and isolated. The Examiner admits that Hamilton does not teach tomato transformation.

The Examiner's contentions regarding the other references are set forth above.

From this the Examiner concludes that it would have been obvious to the skilled artisan to use the transformation-mediated method of plant transformation with tomato genomic DNA fragments from a DNA library taught by Hamilton and to modify that method by incorporating the tomato genomic DNA library taught by Hamilton et al., the *Agrobacterium*-mediated tomato transformation method taught by Frary et al., and the tomato ripening mutant plants taught by Tigchelaar et al. for the selection of those genomic clones containing ripening genes; given the suggestion by Hamilton to broadly apply her methods to dicots and the suggestion by Hamilton et al. to use the *Agrobacterium*-mediated transformation of plants with plant genomic fragments for the identification of new genes via phenotypic complementation. Applicants respectfully traverse.

As a preliminary matter, Applicants note that claims 2-4 have been canceled, thereby obviating the rejections based on these claims.

Applicants point out that Hamilton (US 5,977,439) suggests using the DNA library for complementation-type testing. That is, the genomic DNA used in the library constructed is pre-selected for the presence of a particular gene with known function (e.g. viral resistance). In addition, Hamilton et al. discloses selection of the library using kanamycin resistance as shown in Figure 2 of the citation. In other words, genomic fragments are not introduced randomly in the either of these methods, unlike the feature of the present invention. Consequently, Hamilton and Hamilton et al. fail to teach or suggest one of the essential features of the present invention. As Frary et al. or Tigchelaar et al. do not compensate for this failure, the Examiner has not made a prima facie case of obviousness. Thus, Applicants respectfully request reconsideration and removal of this rejection.

*Lazo et al. in combination with Valvekens et al and Haughn et al.*

The Examiner has rejected claims 1-4 over Lazo et al. in combination with Valvekens et al and Haughn et al. The Examiner's contentions regarding Laze et al. appear above. The Examiner admits that Lazo et al. do not teach the transformation of *Arabidopsis* cells followed by the regeneration of whole transgenic *Arabidopsis* plants.

With respect to Valvekens et al., the Examiner contends that this reference teaches an *Agrobacterium*-mediated method of *Arabidopsis* root tissue comprising cells, followed by the regeneration of whole transformed *Arabidopsis* plants from the transformed cells.

The Examiner contends that Haughn et al. teach the herbicide-resistant *Arabidopsis* strain GH50.

The Examiner then concludes that it would have been obvious to a skilled artisan to use the *Agrobacterium*-mediated transformation of herbicide-sensitive *Arabidopsis* plants with genomic DNA fragments as taught by Lazo et al., and to modify that method by incorporating



the particular transformation method of Valvekens et al. and the genomic fragments from the herbicide resistance gene from the genomic clones containing it, as suggested by Lazo et al. Applicants respectively traverse.

As a preliminary matter, Applicants note that claims 2-4 have been canceled, thereby obviating the rejections based on these claims.

Valvekens et al. disclose obtaining kanamycin resistant plant by transformation of *Arabidopsis* root explant via the *Agrobacterium*-mediated method and selection transformants using kanamycin resistance, followed by regeneration of the plant.

As described above, the Lazo et al. method uses a gene with known function (i.e. herbicide resistance) for plant transformation; it fails to disclose introduction of DNA whose function is unknown. As Valvekens et al. and Haughn et al. do not compensate for this failure, the Examiner has not made a prima facie case of obviousness. Thus, Applicants respectfully request reconsideration and removal of the rejections.

In conclusion, none of the references cited in support of obviousness of the present invention teach or suggest at least one of the essential features of the invention. Specifically, all of the references are silent on construction a genomic library without using a preliminary selection step for the genomic DNA fragments and introducing the genomic fragments randomly. Therefore, Applicants request removal of all of the rejections.

#### Conclusion

In view of the above remarks, all of the claims are submitted as defining non-obvious, patentable subject matter. Reconsideration of the rejections and allowance of the claims are respectfully requested.

In view of the above remarks, all of the claims are submitted as defining non-obvious, patentable subject matter. Reconsideration of the rejections and allowance of the claims are respectfully requested.


Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Susan W. Gorman, Registration No 47,604 at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

Applicants respectfully request a two-month (2 month) extension of time. The Commissioner is hereby authorized to charge Deposit Account No. 02-2448 in the amount of \$490.00 for the fee required under 37 C.F.R. § 1.117(a)(2).

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to our Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. § 1.16 or under § 1.17; particularly, extension of time fees.

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Respectfully submitted,

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